Welch Allyn

K132808

P 1/16

510(k) Summary

[As described in 21 CFR 807.92]

Submitted by:	Welch Allyn Inc. 4341 State Street Road Skaneateles Falls, NY 13153-0220
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Date Prepared:	September 9, 2013
Trade Name:	Connex® Vital Signs Monitor 6000 Series 901060 Vital Signs Monitor
Common Name:	Monitor, physiological, patient (without arrhythmia detection or alarms)
Classification Reference:	Class II, monitor, physiological, patient (without arrhythmia detection or alarms) (21 CFR 870.2300, Product Code MWI)
Predicate Device:	Connex® Vital Signs Monitor 6000 Series 510(k) Number: K121013 Electrocardiograph, 21 CFR 870.2300 Class II, MWI

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Description of the Device:

The Welch Allyn Connex® Vital Signs Monitor 6000 Series (CVSM) is designed to provide a scalable, modular system of components which can be configured to address the needs for vital signs spot checking and continuous monitoring.

The Welch Allyn Connex® Vital Signs Monitor 6000 Series monitor is intended to be used by clinicians and medically qualified personnel for measuring or monitoring patient vital signs. The particular vital sign measurements available are determined by the sensor/processing modules installed into the base unit including;

- NIBP Module provides measurements of noninvasive blood pressure and pulse rate,
- SpO_2 Modules from Nellcor and Masimo provide pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin,
- The Masimo SpO_2 Module can also provide hemoglobin measurements (SpHb, SpHbv) and acoustic respiration rate (RRa),
- The Temperature Module measures body temperature in normal and axillary modes of neonatal, pediatric, and adult patients.
- The Oridion Capnography Module equipped systems are also capable of carbon dioxide (CO_2), respiration rate (RR) and calculation of Integrated Pulmonary Index (IPI) measurements,
- The EarlySense Module provide users the option of continuous and contact-less monitoring of respiration rate, heart rate and patient movement. The addition of this Module is the subject of this 510(k).

The CVSM can also display and transmit patient data that is electronically or manually entered from external and accessory devices, e.g., weight and height data, barcode scanner, IR temperature, and other patient or facility information. Data can be transmitted electronically via USB, wired Ethernet, or wireless communications, including, for example, to electronic record systems and for remote display and alarming (e.g., central station).

Indications for Use:

The Connex® Vital Signs Monitor 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients for:

- noninvasive blood pressure,
- pulse rate,
- noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and
- body temperature in normal and axillary modes.

The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments.

The optional Masimo Rainbow SET® Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, total hemoglobin concentration (SpHb), and/or respiration rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

The optional Oridion module and accessories are intended for the continuous non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric and adult patients in hospitals and hospital type facilities.

The optional Oridion module also provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

Optional compatible weight scales (e.g., Health o meter®) can be used for height, weight, and BMI input.

The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting.

The EarlySense (Everon) module is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, in a hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition.

This product is available for sale only upon the order of a physician or licensed health care professional.

Contraindications:

This system (all configurations) is not intended to be used:

- on patients connected to heart/lung machines
- on patients being transported outside a healthcare facility
- within the controlled access area of MRI equipment
- in a hyperbaric chamber
- in the presence of flammable anesthetics
- in the presence of electrocauterization devices

Systems configured with EarlySense are not intended to be used:

- on patients for whom proper positioning cannot be achieved or maintained
- on patients who do not meet the weight limits tested or specified

Technological Characteristics:

The fundamental hardware and mechanical aspects of the CVSM itself remain the same as the predicate CVSM device cleared under K121013. As noted above, this special 510(k) is for minor software modifications to integrate and display signals from the cleared EarlySense module on the CVSM system. No changes were made to the EarlySense motion sensing technology as cleared; the only changes that are the subject of this submission are the modifications to the CVSM to accommodate integration of the EarlySense module.

Non-Clinical Tests:

The Welch Allyn Connex® Vital Signs Monitor 6000 Series was tested to evaluate its safety and effectiveness based on the following standards:

Standard	Version	Title
EN/IEC 60601-1	2nd Edition 1988	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
EN/IEC 60601-1-2	2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-1-4	1996	Medical Electrical Equipment - Part 1-4: general requirements for safety: General requirement for programmable Electrical Medical System
IEC 60601-2-49	2001	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
IEC 60601-1-8	2003	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: Alarm systems - Requirements, tests and guidances - General requirements and guidelines for alarm systems in medical equipment
IEC 62304	2006	Medical Device Software - Software Life Cycle Processes
EN/ISO 14971	2007	Medical Devices – Application of Risk Management to Medical Devices

Additional performance Bench Testing:

Report DIR --- Description	Objective of the Test	Conclusions
60054949 CVSM ES- 60601-1-2 Electromagnetic Compatibility test	Test the device per 60601-1-2 to ensure that the device meets the requirements for Electromagnetic Compatibility	Pass
60054591 Mobile Stand Threshold	The purpose of this test is to verify that the product is capable of withstanding the stresses caused by rough handling as defined by IEC 60601-1:2005)	Pass
60056145 Mobile Stand Tilt	The purpose of this test is to verify that the product is stable on a stand as defined by IEC 60601-1:2005	Pass
60056145 Shock and Vibration Test	To verify product safety and performance after exposure to shock and vibration.	Pass
60056405 Thermal Shock Test	To verify product performance after the thermal shock conditions specified in Applied standards.	Pass
60056431 Operating Environmental Test (Temperature and Humidity)	To verify product safety and performance within the specified temperature and humidity environment.	Pass
60056898 Ambient Characterization Test	The purpose of this test is ensure that the module level components do not exceed each of their operating temperatures when integrated into the Platform Device and exposed to the operating temperature limits of that device.	Pass
60056476 Functional Drop	To verify product safety and performance after exposure to free fall.	Pass
60055061 EarlySense label wipe Test	To determine whether the chemicals used to clean the EarlySense module will degrade components, materials, or printing.	Pass
60056426 VVP Device Weight Test	To verify the configured Platform device weight.	Pass

60056945 Device Ship Test ISTA-2A	Ensure device, enclosed in the selected shipping container, meets ISTA 2A 2011 specifications.	Pass
60042214 Battery Use Cycles Per Charge– Continuous Monitoring	Verify that the battery shall operate for a minimum of 2 hours under the continuous monitoring use case conditions specified in PMP PAS 60028508 Section 4.4.	Pass
60054951 Electrical Safety test	To confirm the device meets the requirements defined in IEC 60601-1	Pass
60054952 Industrial Design Specification Analysis	The objective of this analysis is to verify via unit and documentation inspection that the CVSM ES Early Sense equipped device has met the requirements of the Industrial Design Specification.	Pass
60054953 CVSM ES Shipping Container Labeling Verification	Verify the CVSM ES and ES Sensor device shipping containers are labeled according to the required specifications.	Pass
60042215 PMP BOM Verification	The objective of this test is to verify that the released CVSM ES BOM includes the specified components identified within the requirements being tested section of this test. This is not a functional test, it is intended as a device inventory to ensure models can be built that will support the features indicated.	Pass

60056673 Connex Vital Signs Monitor ES Design Validation	The purpose of this document is to describe Pre-Summative Validation and Summative Validation testing that will be performed with the Connex SMS ES System (Connex RMS with the integration of Early Sense Technology). Connex SMS ES is comprised of Connex Central Station (CS ES) and the Connex Vital Signs Monitor (CVSM ES). Pre-Summative Validation will be Phase I and Summative Validation will be Phase II. The intent of Phase II is to verify and validate that the Connex SMS ES System meets its usability requirements as defined in the *Connex CS Usability Specification* (DIR 60042476) and the CVSM *Usability Specification Document* (DIR 60029496). The software version tested during Phase II will be production equivalent product. This testing also supports the usability and human factors testing requirements for both Connex ES and CVSM ES.	Pass
60056676 Connex Vital Signs Monitor ES Directions For Use Validation	The intent of Phase II is to verify and validate that the Connex SMS ES System (Connex CS with integration of Early Sense Technology and CVSM ES) Directions for Use meets their usability requirements as defined in the *Connex CS Usability Specification* (DIR 60042476) and the CVSM *Usability Specification Document* (DIR 60029496). No patients will be enrolled in this study.	Pass
60047144 Thermal Shock – 25 cycle	To identify design flaws or behaviors that may occur as a result of the device being exposed to stimulus beyond what is specified within the device thermal shock requirements.	Pass

Clinical Performance Data:

No clinical studies were utilized for the purpose of obtaining safety and effectiveness data.

Device Comparison Table:

The Welch Allyn Connex® Vital Signs Monitor 6000 Series is substantially equivalent in operation and performance to the Welch Allyn Vital Signs Monitor 6000 Series monitor (K121013).

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
Device Name	Connex® VSM 6000 Series	Connex® VSM 6000 Series	Same
Manufacturer	Welch Allyn, Inc.,	Welch Allyn, Inc.,	Same
510(k) Number	K121013	N/A	N/A
Product Code	MWI	MWI	Same
Regulation Name	870.2300 – Cardiac monitor (including cardiotachometer and rate alarm)	870.2300 – Cardiac monitor (including cardiotachometer and rate alarm)	Same
Indications For Use	Welch Allyn VSM 6000 Series The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients for: - noninvasive blood pressure, - pulse rate, - noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and - body temperature in normal and axillary modes. The most likely locations for patients to be monitored are general medical and surgical	Welch Allyn Connex ® VSM 6000 Series The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients for: - noninvasive blood pressure, - pulse rate, - noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and - body temperature in normal and axillary modes. The most likely locations for patients to be monitored are general medical and surgical	

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	floors, general hospital, and alternate care environments.	floors, general hospital, and alternate care environments.	
	The optional Masimo Rainbow SET® Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, total hemoglobin concentration (SpHb), and/or respiration rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.	The optional Masimo Rainbow SET® Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, total hemoglobin concentration (SpHb), and/or respiration rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.	
	The optional Oridion module and accessories are intended for the continuous non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric and adult patients in hospitals and hospital type facilities. concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric, and adult patients in hospitals and hospital type facilities.	The optional Oridion module and accessories are intended for the continuous non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric and adult patients in hospitals and hospital type facilities. concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric, and adult patients in hospitals and hospital type facilities.	Same
	The optional Oridion module also provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric	The optional Oridion module also provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric	

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.	patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.	
	The IPI is an adjunct to, and is not intended to replace, vital sign monitoring. Optional compatible weight scales (e.g.,Health o meter®) can be used for height, weight, and BMI input. The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting. This product is available for sale only upon the order of a physician or licensed health care professional.	The IPI is an adjunct to, and is not intended to replace, vital sign monitoring. Optional compatible weight scales (e.g.,Health o meter®) can be used for height, weight, and BMI input. The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting. **The optional EarlySense® (Everon) System is intended for continuous measurement of respiration rate, heart rate, and movement in an automatic contact-less manner, in a hospital or clinic setting. The system is indicated for use in children, adolescents, and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during**	Same (The base intended use remains the monitoring of patient vital signs. As with previous submissions, the EarlySense Everon Module's cleared indications for use statement is appended unchanged into the CVSM's cleared indications for use statement, as shown by the bold text in the column to the left. The EarlySense (Everon) Module was previously cleared in Early Sense's 510(k) K120465).

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
		sleep and resting condition. This product is available for sale only upon the order of a physician or licensed health care professional.	
Basic Description	The Welch Allyn Connex® Vital Signs Monitor 6000 Series is designed to provide a scalable, modular system of components that could be configured to address the needs for vitals signs spot check and monitoring. It also provides a Framework that can run medical device and non medical software applications The CVSM 6000 Series of monitors are intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. Electronic transmission of date from external accessory devices is supported including temperature, Weight, Height, and BMI. When equipped with Masimo Rainbow SET® Pulse Co-oximeter and accessories may be used for continuous noninvasive monitoring of total hemoglobin concentration and acoustic respiration rate (RRa). Patient monitors equiped with Oridion capnography are also capable of carbon dioxide (CO_2), respiration rate (RR) and calculation of Integrated	The Welch Allyn Connex® Vital Signs Monitor 6000 Series is designed to provide a scalable, modular system of components that could be configured to address the needs for vitals signs spot check and monitoring. The CVSM 6000 Series of monitors are intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. Electronic transmission of date from external accessory devices is supported including temperature, Weight, Height, and BMI. When equipped with Masimo Rainbow SET® Pulse Co-oximeter and accessories may be used for continuous noninvasive monitoring of total hemoglobin concentration and acoustic respiration rate (RRa). Patient monitors equipped with Oridion capnography are also capable of carbon dioxide (CO_2), respiration rate (RR) and calculation of Integrated Pulmonary Index (IPI). Patient monitors equipped with the EarlySense Module	Addition of the EarlySense (Everon) Module to measure respiration rate, heart rate, and movement in an automatic contact-less manner using EarlySense sensors. (cleared by EarlySense in K120465)

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	Pulmonary Index (IPI).	can measure respiration rate, heart rate, and movement in an automatic contact-less manner using EarlySense sensors.	
Target Population	Neonatal, Pediatric, and Adult Patients of any gender.	Neonatal, Pediatric, and Adult Patients of any gender.	Same
Where Used	The product is intended for use in a clinical environment general medical and surgical floors, general hospital, and alternate care environments.	The product is intended for use in a clinical environment general medical and surgical floors, general hospital, and alternate care environments.	Same
Design/Technology	Modular	Modular	Same
Alarms	• Can configure, observe, and respond to an alarm condition.	• Can configure, observe, and respond to an alarm condition.	Same
Nurse Call (wired)	• Can connect to customer nurse call system. Provides NO/NC relay.	• Can connect to customer nurse call system. Provides NO/NC relay.	Same
Patient data management	• Change patient type (adult, pediatric, neonate) • View and enter manual parameters (height, weight, pain, respiration) • Manage patient vitals record • Assign patient and clinician ID to readings • Automated data input of weight, height, and BMI • Connectivity to Electronic Records Management systems for transfer of patient data. • Connectivity to Central Station for continuous patient monitoring and distributed alarms	• Change patient type (adult, pediatric, neonate) • View and enter manual parameters (height, weight, pain, respiration) • Manage patient vitals record • Assign patient and clinician ID to readings • Automated data input of weight, height, and BMI • Connectivity to Electronic Records Management systems for transfer of patient data. • Connectivity to Central Station for continuous patient monitoring and distributed alarms	Same
Memory	• Save patient data to device memory - (300) readings	• Save patient data to device memory - (300) readings	Same
Printer	Yes - 57mm Internal Thermal	Yes - 57mm Internal Thermal	Same
Non-Invasive Blood Pressure (NIBP)	• Display systolic, diastolic, and MAP measurements • Manual and automatic NIBP measurements • Can measure blood pressure as the cuff is inflating • Can measure blood pressure as the cuff is deflating	• Display systolic, diastolic, and MAP measurements • Manual and automatic NIBP measurements • Can measure blood pressure as the cuff is inflating • Can measure blood pressure as the cuff is deflating	Same – the NIBP module has not been modified

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
Algorithm	• Oscillatory BP Algorithm • Fast BP Algorithm	• Oscillatory BP Algorithm • Fast BP Algorithm	Same
Systolic range	• Adult: 30 to 260 mmHg • Pediatric: 30 to 260 mmHg • Neonate: 20 to 120 mmHg	• Adult: 30 to 260 mmHg • Pediatric: 30 to 260 mmHg • Neonate: 20 to 120 mmHg	Same
Diastolic range	• Adult: 20 to 220 mmHg • Pediatric: 20 to 220 mmHg • Neonate: 10 to 110 mmHg	• Adult: 20 to 220 mmHg • Pediatric: 20 to 220 mmHg • Neonate: 10 to 110 mmHg	Same
Pulse rate range using BP	• Adult: 30 to 200 bpm • Pediatric: 30 to 200 bpm • Neonate: 35 to 220 bpm	• Adult: 30 to 200 bpm • Pediatric: 30 to 200 bpm • Neonate: 35 to 220 bpm	Same
Pulse rate accuracy	• ±3 bpm	• ±3 bpm	Same
Thermometer (Thermister probe)	• Welch Allyn SureTemp Plus technology • Temperature range: 80 – 110°F • Either the Predictive (Normal) or Direct (Monitor) Mode • °C or °F • Oral, axillary, rectal	• Welch Allyn SureTemp Plus technology • Temperature range: 80 – 110°F • Either the Predictive (Normal) or Direct (Monitor) Mode • °C or °F • Oral, axillary, rectal	Same – the Thermometer module has not been modified
SpO_2	• Masimo Sensor • Nellcor Sensor • SpO_2 saturation percentage and the pulse amplitude display • Perfusion index • Sat Seconds	• Masimo Sensor • Nellcor Sensor • SpO_2 saturation percentage and the pulse amplitude display • Perfusion index • Sat Seconds	Same – the SpO_2 modules have not been modified
Pulse rate Range and accuracy using SpO_2 determination	• 20 - 250 +/- 3bpm, based with Nellcor SpO_2 parameter • 25 - 240 +/- 3bpm, based on Masimo SpO_2 parameter	• 20 - 250 +/- 3bpm, based with Nellcor SpO_2 parameter • 25 - 240 +/- 3bpm, based on Masimo SpO_2 parameter	Same
O_2 Saturation Range and accuracy	• Nellcor O_2 sat (%) values shall be +/- 3 digits between the range of 70 - 100% • Masimo O_2 sat (%) values shall be +/- 2.0% of the values set between the range of 70 – 100%	• Nellcor O_2 sat (%) values shall be +/- 3 digits between the range of 70 - 100% • Masimo O_2 sat (%) values shall be +/- 2.0% of the values set between the range of 70 – 100%	Same
Total Hemoglobin range and accuracy (SpHb g/dL)	• Masimo Sensor only – Range 0 – 25 g/dL Adults/Infants/Pediatrics 8-17 g/dL + 1 g/dL	• Masimo Sensor only – Range 0 – 25 g/dL Adults/Infants/Pediatrics 8-17 g/dL + 1 g/dL	Same
Acoustic Respiration Rate (RRa)	Masimo hardware provided and software enabled	Masimo hardware provided and software enabled	Same

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	• 4 – 70 +/- 1 breath per minute, adults (>30kg)	• 4 – 70 +/- 1 breath per minute, adults (>30kg)	
Capnography for carbon dioxide (CO_2), respiration rate (RR) measurements and calculation of Integrated Pulmonary Index (IPI).	CO_2 accuracy: 0 to 38 mmHg: ±2 mmHg 39 to 150 mmHg: ±2 (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) Flow rate: 50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume Initialization time: 40 seconds (typical, includes power-up and initialization time) System response time: 2.9 seconds Compensation: BTPS (standard correction used by Microstream capnography during all measurement procedures for body temperature, pressure, and saturation)	CO_2 accuracy: 0 to 38 mmHg: ±2 mmHg 39 to 150 mmHg: ±2 (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) Flow rate: 50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume Initialization time: 40 seconds (typical, includes power-up and initialization time) System response time: 2.9 seconds Compensation: BTPS (standard correction used by Microstream capnography during all measurement procedures for body temperature, pressure, and saturation)	Same – the CO_2 module has not been modified
EarlySense Module	No	Yes	Subject of this submission
Respiration rate	Also provided by Masimo and Oridion Modules	6 to 45 breaths per minute (±4% or ±1.5 breaths per minute, whichever is greater)	Same as cleared by EarlySense in K120465.
Heart Rate	Also provided by NIBP, Nellcor, and Masimo Modules	30 to 170 beats per minute (±4% or ±5 beats per minute, whichever is greater)	Same as cleared by EarlySense in K120465.
Patient Movement	Not previously available.	Movement during defined period (percent of time moving in1.5 minutes) 0 = 0%	Same as cleared by EarlySense in K120465.

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
		L = Up to 40% M = 40% to 60% H = 60% to 80% EH = 80% to 100% (Adult: 0 = 100%, L = 100%, M = 81%, H = 100%, EH = 96% Pediatric: 0 = 100%, L = 100%, M = 81%, H = 86%, EH = 94%)	
External Device Communication Protocol	WACP	WACP	Same
Communication with electronic record systems for alarming and remote monitoring (e.g., central station)	Patient date uploaded episodically to electronic record systems. SpO_2 and Pulse Rate continuous monitoring and interval measurements of NIBP and Temperature	Patient date uploaded episodically to electronic record systems. SpO_2 and Pulse Rate continuous monitoring and interval measurements of NIBP and Temperature. Interface also allows clinician to manually enter Patient notes.	Same except includes modified interface that allows clinicians to manually enter patient notes.
Display type	LCD Touch Screen	LCD Touch Screen	Same
Barcode scanner	Yes The monitor enables the scanning of patients' and/or clinicians' barcodes to enter identification information. The barcode scanner supports linear and 2D barcodes.	Yes The monitor enables the scanning of patients' and/or clinicians' barcodes to enter identification information. The barcode scanner supports linear and 2D barcodes.	Same
Sterility	Device not supplied Sterile	Device not supplied Sterile	Same
Power source	100 -240 V ac 50/60 Hz	100 -240 V ac 50/60 Hz	Same
Battery Power	• Yes • Level of Charge indicator • Lithium ion	• Yes • Level of Charge indicator • Lithium ion	Same

Conclusion

Based on the information presented in this 510(k) premarket notification the Connex® Vital Signs Monitor 6000 Series(CVSM) is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed devices (K121013) citied in this submission. The differences noted between the CVSM and the predicate devices do not impact safety or effectiveness based on the successfully conducted testing of the modified device. The hardware, software, and mechanical aspects of the CVSM itself remain the same as the cleared device (Vital Signs Monitor – VSM 6000 Series, K121013, S.E. date July 26, 2012) except as described below. The modification is to make the EarlySense module available on the CVSM to provide continuous and contact-less monitoring of respiration rate, heart rate, and movement. The software of the CVSM has been modified to enable display of the Early Sense measurements, which are received by CVSM via the same USB communications used to receive data from the currently available modules. The module is the same form factor as the current modules. EarlySense has incorporated sensor processing system into this format of a Connex® Vital Signs Monitor 6000 Series module. EarlySense changed the case of their components to fit the Connex® Vital Signs Monitor 6000 Series platform. It follows the same software communication format as our currently available modules. The fidelity of these data transfers were tested in our design control process. Like the predicate CVSM device, this version of the CVSM can transfer acquired data electronically via USB, wired Ethernet, or wireless communications to other locations. Like the CVSM cleared in K121013, this version of the CVSM can transmit data continuously for secondary remote viewing and alarming (e.g., central station). Also included in this version of CVSM are minor software and connectivity enhancements to improve performance and customer experience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

November 20, 2013

Welch Allyn, Inc.
Mr. Kevin Crossen
Director of Regulatory Affairs
4341 State St. Rd.
P.O. Box 220
Skaneateles Falls, NY 13153-0220 US

Re: K132808
Trade/Device Name: Connex Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)
Regulatory Class: II (two)
Product Code: MWI
Dated: October 24, 2013
Received: October 25, 2013

Dear Mr. Kevin Crossen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K_____

Device Name: Welch Allyn Connex® Vital Signs Monitor 6000 Series

Indications for Use:

The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients for:

- noninvasive blood pressure,
- pulse rate,
- noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and
- body temperature in normal and axillary modes.

The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments.

The optional Masimo Rainbow SET® Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, total hemoglobin concentration (SpHb), and/or respiration rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

The optional Oridion module and accessories are intended for the continuous non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric and adult patients in hospitals and hospital type facilities.

Prescription Use ___x___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Date: 2013.11.20 10:37:53 -05'00'

Indications for Use (Continued)

The optional Oridion module also provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

Optional compatible weight scales (e.g., Health o meter®) can be used for height, weight, and BMI input.

The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting.

The EarlySense (Everon) module is intended for continuous measurement of respiration rate, heart rate and movement. in an automatic contact-less manner, in a hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition.

This product is available for sale only upon the order of a physician or licensed health care professional.